

REMARKS

Claims 1-18 were examined in the February 7, 2006 Final Office Action.

The claims stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement, and under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,952,370 to Cummings, *et al.* ("Cummings"), in view of U.S. Patent No. 6,572,819 B2 to Wu, *et al.* ("Wu"). The claims also stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over three applications assigned to the owner of the present application.

1. Double Patenting Rejections: In response to the double patenting rejections, the Applicants are submitting herewith a Terminal Disclaimer, with the required fee. Withdrawal of the provisional double patenting rejections is respectfully requested.

2. Section 112 Rejection: As discussed in the Examiner Interview in these related cases, in order to satisfy the Examiner's concern that the prior recitation ("several seconds") might be read in the Cummings reference relatively slow process (measured in minutes), the Applicants amended the pending claims to recite a numerical time limitation on the amount of time for the expansion and condensation of the sterilizing vapor ("less than ten seconds"). It was the Applicants' understanding from the discussions in the Interview that this amendment was sufficient to overcome the pending rejection based on Cummings. In view of the § 112, first paragraph rejection and first-action Final rejection received in the February 7, 2006 Office Action, the Applicants have

amended claims 1 and 11 to restore the “several seconds” limitation, thus rendering the pending § 112, first paragraph rejection moot. Withdrawal of the pending § 112 rejection is respectfully requested.

3. Section 103(a) Rejection: The Applicants respectfully traverse the rejection of claims 1-18 under § 103(a) as unpatentable over Cummings and Wu, on the grounds that these references fail to teach or suggest all the features of the present invention recited in independent claim 1, and the absence of any suggestion or motivation to combine the references.

In addition to the amendment discussed above, claim 1 also has been amended to recite that after the formation of the “sudden” condensation layer on the objected to be sterilized, “within seconds, after a short reaction time” the condensation is “followed by completely suctioning off the condensation layer by further evacuation of the sterilization chamber at a pressure below 10mb.” Claim 1 further has been amended to recite that “the surfaces of the sterilization chamber are smooth and made of poor heat-conducting, water-repellant material.” These amendments are consistent with the original disclosure. *See, e.g.*, Specification at 5, ¶ 4 (“... suddenly condenses”; “... drawn off within seconds”); at 5, ¶ 5 (“...short reaction time”; “...a pressure of below 10mb”); at 3, ¶ 5 (“...the surfaces should be smooth”).

The purpose of these amendments is to focus on the present invention’s very fast sterilization process, wherein the reaction time and suctioning off of the condensation layer occurs in only a matter of seconds. Further, it is intended to clarify that the surfaces of the sterilization chamber are configured in a special

way, namely smooth, with use of poor heat-conducting, water-repellant material.

With regard to the latter, the Applicants respectfully submit that one of ordinary skill would not have considered the Wu reference, and further would not have perceived a suggestion or motivation to combine this reference with the Cummings reference. Wu describes a sterilization *container* which is intended to be put into a sterilization *chamber*, *i.e.*, the design concerns for a sterilization container are very different from those of a sterilization chamber (*e.g.*, through-wall heat transfer is not a significant issue with a container). Further, Wu teaches the use of silicone rubber in a substantial portion of its container. As noted in the fourth paragraph at page 4 of the present Specification, one of ordinary skill in the art would not consider use of silicone rubber for a sterilization chamber wall surface because silicone rubber catalytically decomposes hydrogen peroxide, a characteristic which would greatly interfere with the operation of the present invention's sterilization process.

There also is no suggestion in Wu or Cummings for the combination of these references, *i.e.*, to make the surfaces of the Cummings sterilization chamber smooth and from a poor heat-conducting, water-repellent material as recited in amended claim 1. Cummings teaches that the walls of its centrifuge chamber 14 are made of a material which has a good heat conducting properties. *See, e.g.*, Cummings Fig. 1 (one of ordinary skill would recognize that the chamber cooling device ("refrigeration coils 58") can only properly cool down the centrifuge chamber 14 (and thereby cool the objects inside) if the walls of chamber have good heat conducting properties). There is nothing in Cummings

or Wu which suggests that Cumming's sterilization process should be modified by the introduction of a silicon rubber or plastic container material which does not possess good heat transfer properties; indeed, such a change would *inhibit* the operation of the Cummings apparatus. Thus, the insulating character of Wu's container materials teaches *against* its combination with Cummings, as such a combination would constitute an impermissible change to a principle of operation of Cummings. MPEP § 2143.01. A skilled person in the art therefore would not have considered combining the Cummings and Wu references.

As a separate grounds for withdrawal of the pending rejection, Cummings fails to teach or suggest the present invention's nearly instantaneous, essentially object-temperature-independent sterilization process, in which the condensation of the sterilizing agent is achieved by very quick expansion of the vapor compound. Cummings' slow sterilizing agent admission and expansion process (measured in minutes, rather than seconds) makes it necessary to cool down the objects to be sterilized in order to ensure condensation will eventually be achieved. In addition to the express statements in Cummings regarding the time required for its slow condensation process (discussed in the Applicants' previous remarks), one of ordinary skill would recognize that Cummings' object cooling is inconsistent with an abrupt condensation process, *i.e.*, object cooling is not required in such a process. Thus, there is nothing in this reference which either teaches the present abrupt condensation process, or provides any motivation for one of ordinary skill – lacking hindsight knowledge of the present invention – to fundamentally alter Cummings by replacing its relatively slow condensation

process with the present essentially instantaneous process.

Finally, as to the issue of use of the term “several seconds,” the Applicants respectfully submit the following. As noted above, the presently pending claims are drawn to a sudden expansion sterilization process which is essentially instantaneous in its operation, with expansion and condensation occurring “within several tenths of a second up to several seconds such that the vapor composite cools to below the hydrogen peroxide dew point and condenses on all accessible surfaces of the objects to be sterilized and on the surfaces of the sterilization chamber in the form of a sudden condensation layer.” Removal of the condensation layer occurs “within seconds, after a short reaction time followed by completely suctioning off the condensation layer by further evacuation of the sterilization chamber at a pressure below 10mb.”

The Applicants submit that one of ordinary skill would unquestionably recognize that expansion and condensation “within several tenths of a second up to several seconds” describes a process which is fundamentally different from that taught by Cummings (and conversely, that claims drawn to such a process do not read on Cummings’ process). A skilled individual would immediately recognize that the vapor compound has to very quickly expand in the sterilization chamber if condensation is to occur on objects which are not cooled down, as in Cummings. One of ordinary skill further would recognize that this is because the *as-claimed* process is a *fundamentally different thermodynamic process* than that taught by Cummings (*i.e.*, abrupt, adiabatic expansion and condensation vs. Cummings’ condensation by heat extraction by cooled target

objects). Thus, the current claim limitation “wherein expanding and condensing the vapor compound takes place within several tenths of a second up to several seconds such that the vapor composite cools to below the hydrogen peroxide dew point and condenses on all accessible surfaces of the objects to be sterilized and on the surfaces of the sterilization chamber in the form of a sudden condensation layer” distinguishes the pending claims over the Cummings process. Moreover, when read in the context of the entire specification, as required, the present claim language is sufficient definite for clear understanding the phase “within several tenths of a second up to several seconds” by those of skill in the art, and in particular how the claims differ from Cummings. The Applicants respectfully submit that a more definitive (*e.g.*, numerical) recitation is not required. *Accord* MPEP § 2173.02 (the Examiner “should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression ... should be permitted *even though the claim language is not as precise as the examiner might desire.*” (underline in original; italics added); claim language to be analyzed in light of (A) the content of the disclosure, (B) the teachings of the prior art, and (C) the “claim interpretation *that would be given by one possessing the ordinary level of skill in the pertinent art...*” (italics added)).

For the foregoing reasons, the Applicants respectfully submit that Cummings and Wu fail to teach all of the features of the present invention recited in claims 1-18 for which these references are cited; that one of ordinary skill would not have attempted looked to either of these references to obtain the

present invention; that there was no suggestion or motivation for their combination; and finally, that the "within several tenths of a second up to several seconds" limitation defines a patentably distinct process not suggested by Cummings. Accordingly, claims 1-18 are patentable over these references under § 103(a). Reconsideration and withdrawal of the pending § 103(a) rejection is respectfully requested.

CONCLUSION

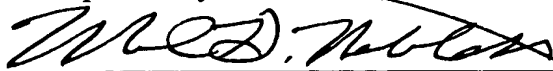
The Applicants submit that claims 1-18 are in condition for allowance. Early and favorable consideration, and issuance of a Notice of Allowance for claims 1-18 is respectfully requested.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 029082.53055US).

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